Remarks

1. Support for the Amendments

Claims 23 and 24 have been canceled without prejudice to or disclaimer of the subject matter contained therein. Claims 10-15, 17-18, 20-22 and 25 have been amended. Support for the foregoing claim amendments may be found throughout the specification, for example at page 23, line 4 through page 29, line 22, in the sequence listing, Table A, and in the original claims. Upon entry of the foregoing amendments, claims 10-18, 20-22 and 25 are pending in the present application. No new matter enters by these amendments.

The specification has been amended to explicitly reference the Sequence Listing on computer readable form in the present application. The specification has also been amended to remove the alleged embedded hyperlinks and/or other forms of browser-executable code. The URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. The specification as amended does not contravene stated PTO policy of prohibiting live web links to other web pages, which might be commercial. (MPEP, § 608.01 (d)). No new matter enters by these amendments.

2. *Rejection of Claims 10-18, 20-22 and 24-26 Under 35 U.S.C. § 101*

Claims 10-18, 20-22 and 24-26 have been erroneously rejected under 35 U.S.C. § 101 for allegedly not being supported "by a specific, substantial and credible utility or by a well established utility." Office Action at page 3. Applicants respectfully disagree with this assertion. As Applicants have cancelled claim 24, and have previously cancelled claim 26 in the Amendment dated October 10, 2002 (*see also* Advisory Action and Interview Summary mailed October 24, 2002 (collectively, "First Advisory Action"), and Advisory Action and Interview Summary mailed November 24, 2002 ("Second Advisory Action"), the following arguments are addressed to pending claims 10-18, 20-22, and 25.

The Examiner acknowledges that Applicants have disclosed and argued several utilities for the nucleic acid molecules of the present invention, for example, to detect the presence or absence of polymorphisms, as probes for expression profiling, gene mapping, detection of gene expression, molecular weight markers, chromosomal markers, etc. Office Action at pages 3-4; Office Action mailed November 21, 2000 (Paper Number 7), at page 5. However, the Examiner contends that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because "these are general uses (purposes) applicable to the general class of nucleic acids and are not specific to the SEQ ID NO's claimed." *Id.* at page 3.

As Applicants have previously stated, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify a polymorphism in a population of maize or soybean plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit"

may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses several uses for the claimed nucleic acid molecules, including use a nucleic acid molecule markers and probes (*see, e.g.,* specification at page 58, lines 8-11, and at page 69, line 19 through page 73, line 14); to identify and obtain nucleic acid homologues (*see, e.g.,* specification at page 82, line 3 through page 83, line 13); in microarrays as gene-specific targets (*see, e.g.,* specification at page 102, line 21 through page 105, line 14); to identify the presence or absence of a polymorphism (*see, e.g.,* specification at page 84, line 18 through page 92, line 11); use to transform plants and other organisms (*see, e.g.,* specification at page 110, line 7 through page 128, line 21; at page 132, line 11 thorough page 133, line 2; and at page 158, line 9 through page 159, line 10); to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule (*see, e.g.,* specification at page 97, line 22 through page 102, line 13); and use to overexpress or suppress a desired protein (*see, e.g.,* specification at page 128, line 17 through page 131, line 9).

The Examiner acknowledges that the nucleic acids of the present invention may be used as probes, to detect the presence or absence of polymorphisms, and in expression studies, however the Examiner denigrates these utilities by claiming they are not "useful" because they are "applicable to the general class of nucleic acids". Office Action at page 3. Furthermore, although the Examiner admits that Applicants have pointed out that the nucleic acid molecules of the present invention comprise sequences that encode enzymes of the tocopherol pathway or fragments thereof, the Office Action alleges that the specification "does not disclose that any of the claimed nucleic acid sequences is actually known to encode an enzyme of the tocopherol pathway" and that "it is not known or

disclosed whether any of the claimed nucleic acid sequences is known to be involved in *modulation* of tocopherol or vitamin E synthesis." Office Action at page 4 (emphasis in original).

The Examiner's assertions are not correct. The Examiner appears to be arguing that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. As stated in Applicants' Appeal Brief dated October 10, 2002 ("Appeal Brief"), that position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Furthermore, the specification clearly asserts that the nucleic acid molecules of the present invention encode maize or soybean tocopherol synthesis pathway enzymes or fragments thereof. *See, e.g.*, specification at page 21, line 2 through page 29, line 22, page 235, line 8 through page 236, line 15 (Example 4), Table A and the sequence listing. The specification also explains the interrelationship of the enzymes involved in the tocopherol synthesis pathway (*see, e.g.*, specification at page 1, line 17 through page 11, line 23). In addition, the specification also discloses the methods used to analyze each of the claimed nucleic acid molecules and its association with the tocopherol synthesis pathway. *See, e.g.*, specification at page 16, line 21 through page 17, line 17; page 171, lines 4-10; and page 235, line 8 through page 236, line 2 and Table A. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify markers and isolate promoters in the tocopherol synthesis pathway of maize or soybean plants upon reading the present specification.

The Examiner argues that the claimed nucleic acid molecules lack utility apparently because one would allegedly not be able to recognize an appropriate ATG codon or ORF for the claimed nucleic acid molecules. *See* Office Action at page 4. However, as stated above, one of ordinary skill on the art would clearly be able to ascertain these elements based on Applicants' disclosure (*see, e.g.,* specification at page 171, lines 4-10) and tools available to practitioners in the art, *e.g.,* BLASTX. Moreover, the specification discloses that the nucleic acid molecules of the present invention encode tocopherol synthesis pathway enzymes or fragments thereof. Therefore, a complete ORF or start codon is not necessary for every claimed nucleic acid molecule. Furthermore, a complete ORF is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, *i.e.,* as probes, to detect the presence or absence of polymorphisms, and in expression studies, all of which the Examiner acknowledges have been asserted in the specification.

In addition, for these reasons, the Examiner's assertion that homology "alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence" is irrelevant. Office Action at page 4. The Examiner has provided references supporting only the general controversy in the art regarding homology, but has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. A broad assertion of "unpredictability" in the art is not sufficient to reject the claimed invention for lack of utility.

The Examiner has provided no evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utilities and, as such, has not met the burden of challenging the disclosed utilities. *Cf. In re Swartz,* 232 F.3d 862, 863, 56 U.S.P.Q.2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. 48, 51 (C.C.P.A. 1981)). 462, 108 U.S.P.Q. 321, 325 (C.C.P.A. 1956). Furthermore, Applicants do not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons,* 340 F.2d 974, 978, 144 U.S.P.Q. 351, 354 (C.C.P.A.

1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. MPEP § 2164.07. Applicants have met this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

3. *Rejection of Claims 10-18, 20-22 and 24-26 Under 35 U.S.C. § 112, First Paragraph, Enablement*

Claims 10-18, 20-22 and 24-26 were rejected under 35 U.S.C. § 112, first paragraph, as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Office Action at page 5. Applicants respectfully disagree. As Applicants have cancelled claim 24, and have previously cancelled claim 26 in the Amendment dated October 10, 2002 (*see also* First Advisory Action and Second Advisory Action), the following arguments are addressed to pending claims 10-18, 20-22, and 25.

This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate

rejection for lack of enablement). Thus, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

4. *Rejection of Claims 10-18 and 20-24 Under 35 U.S.C. §112, 1st Paragraph: Written Description*

Claims 10-18 and 20-24 have been erroneously rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being described in the specification "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 5. As Applicants have cancelled claims 23 and 24, the following arguments are addressed to pending claims 10-18 and 20-22.

The Examiner does not dispute that Applicants have possession of and have adequately described SEQ ID Nos: 1, 100, 147, 153, 158, 161, 180, 199 and 232.[1] Office Action at page 5. However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that "claims 10-22 and 24 recite open claim language" and that "claims 10-11, 13-15, and 17-21 specifically recite 'fragments', and are also directed to encompass sequences which hybridize to [the claimed SEQ ID NOs]."[2] Office Action at page 5. According to the Examiner, the open claim language would "encompass gene sequences, sequences that hybridize, corresponding sequences from other species, derivatives, allelic variants, splice variants, and so forth." *Id.* at pages 5-6. Apparently, the Examiner argues that "[t]he specification provides insufficient written description to support the genus encompassed by the claims." *Id.* at page 6. Applicants respectfully disagree.

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[1] Applicants note that the nucleic acid sequence of SEQ ID NO: 184 has also been disclosed in the present specification.

[2] Applicants note that pending claims 10-11, 13-15, and 17-21 do not specifically recite "fragments" of the claimed nucleic acid molecules. Rather, claim 10 and its dependents require "[a]n isolated nucleic acid molecule comprising a sequence that hybridizes under conditions of 2.0 X sodium chloride/sodium citrate (SSC) at about 65°C to a nucleic acid molecule having a sequence selected from the group consisting of SEQ ID NOs: 100, 147, 153, 180, 199, 232 and complements thereof."

This argument flies in the face of the existing patent jurisprudence. It is well-established law that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are not specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicants to describe hypothetical claim elements. Applicants' claims do not recite open reading frames and, accordingly, need not describe them. Applicants need only describe the claimed invention, and have done so in the present application.

As Applicants have previously stated, the purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of nucleic acid molecules comprising nucleic acid sequences selected from the group of SEQ ID NOs: 1, 100, 147, 153, 161, 180, 199, 232, 184 and 158, complements thereof, and nucleic acid molecules that hybridize to the claimed SEQ ID NOs under the recited conditions, and therefore, the claimed invention.

Applicant's present disclosure not only provides the nucleic acid sequences required by the claims (*i.e,* SEQ ID NOs: 1, 100, 147, 153, 161, 180, 199, 232, 184 and 158), but further describes that the claimed nucleic acid molecules may include the recited sequence with additional sequences, for example, vectors comprising the claimed nucleic acid molecules (*see, e.g.,* specification at page 111, line 6 through page 119, line

20), hybridization conditions which may be used with the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 60, line 16 through page 61, line 10), and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell (*see, e.g.,* specification at page 119, lines 13-20). The specification also describes, for example, nucleic acid molecules comprising single nucleotide polymorphisms (SNPs) and methods to identify sequences containing them (*see, e.g.,* specification at page 70, line 12 through page 72, line 2), methods for identifying nucleic acid molecules comprising promoter regions and other regulatory elements (*see, e.g.,* specification at page 83, line 14 through page 84, line 17), nucleic acid molecules comprising nucleic acid sequences having conservative substitutions (*see, e.g.,* specification at page 64, line 15 through page 66, line 7), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 76, line 19 through page 77, line 8), plant and other homologue proteins and nucleic acid molecules (*see, e.g.,* specification at page 64, lines 4-9 and page 77, lines 6-22), site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 105, line 15 through page 107, line 7), and references describing the construction, manipulation and isolation of nucleic acid macromolecules (*see, e.g.,* specification at page 163, line 22 through page 164, line 6). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner maintains that "one skilled in the art would not be able to immediately envisage these products or structures." Office Action at page 6.

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. In particular, Applicants have disclosed common structural features, for example the nucleotide sequences of SEQ ID NOs: 1, 100, 147, 153, 161, 180, 199, 232, 184 and 158, and their complements, as well as recited specific hybridization conditions. The respective

common structural feature (the nucleotide sequences of SEQ ID NOs: 1, 100, 147, 153, 158, 161, 180, 184, 199, 232 and their complements) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1.[3] If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not.

Moreover, closely related nucleic acid molecules falling within the scope of claim 10 and its dependents are readily identifiable - they either hybridize under the claimed conditions to SEQ ID NOs: 100, 147, 153, 161, 180, 199 and 232 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

The Examiner also alleges, with respect to claims 23-24, that the specification "does not disclose that SEQ ID NO: 158 is known to encode a maize shikimate dehydrogenase." Office Action at page 6. As Applicants have cancelled these claims in the present amendment, the merits of the Examiner's assertion will not be addressed.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, pending claims 10-18 and 20-23 are supported by an adequate written description pursuant to the requirements of 35

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[3] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA comprises the nucleotide sequence of SEQ ID NO: 100, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 100. *See, e.g.,* claim 13.

U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

5. Rejection of Claim 24 Under 35 U.S.C. § 112, First Paragraph, Enablement

Claim 24 has been rejected under 35 U.S.C. §112, first paragraph, because the subject matter allegedly was not described "in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Office Action at page 7. As Applicants have cancelled claim 24 in the present amendment, the merits of the Examiner's assertion will not be addressed.

6. Rejection of Claims 10 and 23 Under 35 U.S.C. § 102

Claim 10 has been erroneously rejected under 35 U.S.C. § 102(b) over SASAKI (accession No. D23883). Office Action at pages 9-10. According to the Examiner, SASAKI discloses a nucleic acid sequence that exhibits 52.9% similarity to SEQ ID NO: 161 and would therefore hybridize under the claimed conditions. Applicants respectfully disagree that the Office has provided a sufficient showing of anticipation, however in order to facilitate prosecution, Applicants have amended claim 10. As such, the rejection under 35 U.S.C. § 102(b) over SASAKI is rendered moot and withdrawal of this rejection is respectfully requested.

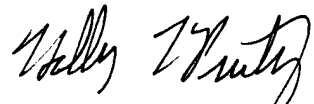
Claim 23 has been rejected under 35 U.S.C. § 102(b) as being anticipated by WENDEL *et al.* As Applicants have cancelled claim 23 in the present amendment, the rejection under 35 U.S.C. § 102(b) over WENDEL is rendered moot and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdrawal the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees in addition to those provided for in the accompanying documents, are due at this time. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.233.

Respectfully submitted,



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